

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|---|----------------------|-------------------------|------------------|
| 09/813,292 | 03/21/2001 | Borge Kringelum | 030307- 0197 | 1783 |
| 75 | 90 07/19/2002 | | | |
| Stephen A. Bent FOLEY & LARDNER Washington Harbour | | | EXAMINER | |
| | | | DAVIS, RUTH A | |
| | 3000 K Street, N.W., Suite 500 Washington, DC 20007-5109 ART UNIT PAPE | | PAPER NUMBER | |
| Washington, 2 | | | 1651 | y |
| | | | DATE MAILED: 07/19/2002 | 8 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| * | | Application No. | Applicant(s) |
|---|--|--|---|
| | | 09/813,292 | KRINGELUM ET AL. |
| | Office Action Summary | Examiner | Art Unit |
| | | Ruth A. Davis | 1651 |
| | The MAILING DATE of this communication a | appears on the cover sheet | with the correspondence address |
| | Ponty | | |
| THE M - Extense after S - If the III - If NO - Failur | PRTENED STATUTORY PERIOD FOR REINALING DATE OF THIS COMMUNICATION Sions of time may be available under the provisions of 37 CFR SIX (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a period for reply is specified above, the maximum statutory period for reply within the set or extended period for reply will, by state of the period by the Office later than three months after the model of the patent term adjustment. See 37 CFR 1.704(b). | reply within the statutory minimum of triod will apply and will expire SIX (6) M | a reply be timely filed thirty (30) days will be considered timely. ONTHS from the mailing date of this communication. ABANDONED (35 U.S.C. § 133). |
| tatus | in the second se | 30 April 2002 . | |
| 1)⊠ | Responsive to communication(s) filed on | This action is non-final. | |
| 2a)⊠ | THIS action to the terms. | was avont for formal r | natters, prosecution as to the merits is |
| 3) | Since this application is in condition for all closed in accordance with the practice un | der Ex parte Quayle, 1935 | C.D. 11, 453 O.G. 213. |
| Dispositi | ion of Claims | | |
| 4)🛛 | Claim(s) 1-26 is/are pending in the applica | ation. | |
| | 4a) Of the above claim(s) is/are with | ndrawn from consideration. | |
| 5)□ | Claim(s) is/are allowed. | | |
| 6)🛛 | Claim(s) <u>1-26</u> is/are rejected. | | |
| 7) | Claim(s) is/are objected to. | | |
| | Claim(s) are subject to restriction a | ind/or election requirement | • |
| Applica | tion Papers | inor | |
| 9) | The specification is objected to by the Exa | miner. | by the Examiner. |
| 10) | The drawing(s) filed on is/are: a) | accepted of b) bolcoted to | abevance. See 37 CFR 1.85(a). |
| | Applicant may not request that any objection The proposed drawing correction filed on | is: a) \(\begin{aligned} \text{approved b} \end{aligned} | disapproved by the Examiner. |
| 11) | The proposed drawing correction fled on | t in reply to this Office action. | |
| _ | If approved, corrected drawings are required | he Examiner. | |
| | The oath or declaration is objected to by the | no Examination | |
| Priority | under 35 U.S.C. §§ 119 and 120 | ioroian priority under 35 U.S | S.C. § 119(a)-(d) or (f). |
| | Acknowledgment is made of a claim for f | oreign priority under 55 514 | |
| á | a) All b) Some * c) None of: | ments have been received | i . |
| | 1. Certified copies of the priority docu | ments have been received | in Application No |
| | 2. Certified copies of the priority doci | uments have been received | been received in this National Stage |
| | application from the Internation | r a list of the certified copie | 5 100 1000. |
| 141 | Acknowledgment is made of a claim for de | omestic priority under 35 U | .S.C. § 119(e) (to a provisional application) |
| | Lating of the foreign langua | age provisional application i | has been received. |
| 15) | a) [] The translation of the loreign language.] Acknowledgment is made of a claim for d | Iomestic priority under 35 L | J.S.C. §§ 120 and/or 121. |
| Attachn | · · | | |
| 1) [] N | lotice of References Cited (PTO-892) lotice of Draftsperson's Patent Drawing Review (PTO- nformation Disclosure Statement(s) (PTO-1449) Paper | 948) 5) No | terview Summary (PTO-413) Paper No(s) otice of Informal Patent Application (PTO-152) her: |
| | 1. To describe Office | Office Action Summary | Part of Paper No. 8 |

Application/Control Number: 09/813,292

Art Unit: 1651

DETAILED ACTION

Applicant's amendment has been received and entered into the case. Claims 25-26 have been added. Claims 1-26 are pending and have been considered on the merits.

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 2. Claims 1-26 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a method for supplying a starter culture, however remain vague and indefinite for reciting "using a subset" because it is unclear how this is a step for supplying a starter culture. Moreover, because the language does not set forth any steps involved regarding "using" a subset of stock inoculum, it is unclear what method/process applicant is intending to encompass.

Claim 1 remains confusing for reciting "for a period of time adjusted sufficiently in size".

Applicant may prefer to replace the phrase "adjusted sufficiently in size" with "sufficient" to more clearly point out the claimed invention.

Claim 5 remains vague and indefinite because the claim appears to claim a ratio of CFUs of the subset of stock inoculum after inoculation into the medium: CFUs of the subset of stock

Application/Control Number: 09/813,292

Art Unit: 1651

inoculum being inoculated. However, applicant argues that the claim reflects the ratio of the concentration of the starter culture: the concentration in the culture medium. As the claim appears to indicate a ratio opposite that argued by applicant, it is unclear which ratio applicant intends to encompass.

Claim 7 remains vague and indefinite because the claim still does not specifically point out what the cultivation medium is. It is reiterated that the claim does not contain a transitional phrase and merely states that the medium "may be" any conventional medium. Applicant may prefer to replace the phrase "may be" with the word "comprises" to more clearly point out the claimed invention.

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Application/Control Number: 09/813,292

Art Unit: 1651

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Page 4

Claims 1-4, 6-7, 11, 17-22 and 24 rejected under 35 U.S.C. 103(a) as being 5. unpatentable over Sing.

Applicant argues that Sing does not teach the method wherein a subset of the stock inoculum is used to inoculate the medium, but that the entire stock inoculum is used. Applicant additionally argues that Sing does not teach harvesting the propagated cells wherein they can be used as additional starter cultures. Finally, applicant argues that the claimed method reduces contamination and variation of cell cultures.

However, these arguments fail to persuade because while Sing does not specifically teach using only a portion of the stock inoculum, Sing does teach inoculating the culture medium with at least 10^9 CFU/g (which is at least 10^8 CFU/g as claimed). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to take a portion of a stock material when following the methods of Sing, such that the disclosed amount is inoculated into the culture medium. Moreover, at the time of the claimed invention one of ordinary skill in the art would have been motivated to inoculate a subset of a stock inoculum, with a reasonable expectation for propagating cells and harvesting the propagated cells. In addition, Sing specifically teaches that the harvested cells are inoculated into a milk to produce dairy products (or are used as the starter culture). Although Sing does not teach the harvested cells can be divided into several new starter cultures, it would been obvious to one of ordinary skill in the art to do so, since such methods were known in the art for making starter cultures. In addition, it is

Application/Control Number: 09/813,292

Art Unit: 1651

pointed out that the claims merely state, "which subset thereof <u>can be</u> used as said starter culture" (emphasis added). The claims do not explicitly require the harvested cells to be divided and used to provide multiple, additional, new starter cultures, therefore the argument is not commensurate is scope with the claim language.

Finally, in response to applicant's argument that the claimed method reduces contamination and variation of the cell cultures, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

For the reasons stated above and those made previously of record, the claims are rendered obvious over Sing et al.

6. Claims 1, 7 and 25 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Czulak.

Applicant does not off any additional arguments other than those stated above. As such, for the reasons stated above and those made in the previous office action, claims 1, 7 and 25 - 26 are rendered obvious over Sing in view of Czulak.

7. Claims 1 and 8 – 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Lizak.

Application/Control Number: 09/813,292

Art Unit: 1651

Applicant does not off any additional arguments other than those stated above. As such, for the reasons stated above and those made in the previous office action, claims 1, 7 and 25 - 26 are rendered obvious over Sing in view of Lizak.

8. Claims 1 and 12 – 16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Vandenbergh and Matsumiya.

Applicant does not off any additional arguments other than those stated above. As such, for the reasons stated above and those made in the previous office action, claims 1, 7 and 25 - 26 are rendered obvious over Sing in view of Vandenbergh and Matsumiya.

9. Claims 1 and 17 – 18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Czulak and Lizak.

Applicant does not off any additional arguments other than those stated above. As such, for the reasons stated above and those made in the previous office action, claims 1, 7 and 25 - 26 are rendered obvious over Sing in view of Czulak and Lizak.

10. Claims 1, 20 and 22 – 23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Rimler and Lizak.

Applicant does not off any additional arguments other than those stated above. As such, for the reasons stated above and those made in the previous office action, claims 1, 7 and 25 - 26 are rendered obvious over Sing in view of Rimler and Lizak.

Application/Control Number: 09/813,292

Art Unit: 1651

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Application/Control Number: 09/813,292

Art Unit: 1651

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad July 16, 2002

PRIMARY EXAMINER